

Appl. No. 09/764,560Atty. Docket No. 8392Amdt. dated November 10, 2003Reply to Office Action of May 8, 2003**REMARKS**

Claims 1-6 and 10-30 are pending in this application and all presently stand rejected. By the amendments presented, Claim 1 has been amended to more specifically define the present invention by requiring that the cationic surfactant comprise a quaternary ammonium halide and by further requiring that the composition comprise cholesterol and that the ratio of cholesterol to cationic surfactant range from about 0.5:1.0 to about 1.5:1.0. Support for this amendment can be found in the Specification on page 15 lines 20-33 to page 16 lines 1-3. Further, Claim 1 has been amended to more clearly define the reactive component and reactive agent, as defined in the Specification on page 3, lines 10-13 and lines 27-33, for which the Examiner has rejected under 35 U.S.C. 112, second paragraph.

The Examiner has raised a rejection to Claim 4 with regard to insufficient antecedent basis for nucleophilic groups. Accordingly, Applicants have amended Claim 4 to provide proper antecedent basis.. The Examiner has raised a rejection to Claim 10 being dependent on Claim 9, which has been previously canceled. Accordingly, Applicants have amended Claim 10 to be properly dependent on Claim 1. Applicants respectfully submit reconsideration of the 35 U.S.C. § 112 claim rejections based on the remarks above.

Double Patenting Rejection

Claims 1-6 and 10-30 have been provisionally rejected under the judicially created doctrine of obvious-type double patenting as being unpatentable over Claims 1-22 of copending application No. 09/799,185 and claims 1-42 of copending application No. 09/764,561. In setting forth this rejection, the Examiner indicated that a timely filed Terminal Disclaimer over these common owned applications would overcome the rejection.

Responsive to this rejection, a Terminal Disclosure under 37 C.F.R. 1.321(c) for the above-entitled application which specifies that the Petitioner disclaims the terminal part of the statutory term of any patent granted on the above entitled application which would extend beyond the expiration date of the full statutory term defined in 35 U.S.C. §154 to §156 and §173 as shortened by any terminal disclaimer filed prior to the grant of any patent granted on pending Application Number 09/799,185 and 09/764,561. Submission of the Terminal Disclaimer thus obviates the provisional obviousness-type double patenting. Applicants confirm that the copending application No. 09/799,185 and 09/747,561 were assigned to the Procter & Gamble Company/ and commonly owned at the time of the invention and is reflected in the assignment record above-identified application (the assignment recorded on April 25, 2002 at reel 012627,

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frame 0181), on pending second Application Number 09/799,185, filed on March 5, 2001 (the assignment recorded on September 12, 2002 at reel 013082, frame 0388) and on pending third Application Number 09/764,561, filed on January 17, 2001 (the assignment recorded on March 25, 2002 at reel 012627, frame 0173)

Invention Synopsis

The present invention relates a treatment composition, comprising: an aqueous continuous phase; a reactive component comprising: a) a reactive agent selected from a compound comprising a reactive group, the reactive group selected from the group consisting of either an electrophilic reactive group selected from the group consisting of halotriazine, haloquinoxaline, halopyrimidine, vinylsulfone, \square -haloethylsulfone, \square -sulfatoethylsulfone, acrylates, methacrylate, acrylamide, methacrylamide, maleimide, epoxide, acylhalide, ester, carbamate, dithiocarboxylic acid ester, alkoxysilane, thiosulfate, anhydride, urea derivative, isothiocyanate, isocyanate, lactone, thiosulfate, isothiuronium, azolactone electrophilic groups and mixtures thereof, or a protected thiol reactive group having the formula



where R is a mono or multivalent cosmetically active functional group, S is sulfur, Pr is a protecting group and m is an integer between 1 and 100; and b) a water immiscible solvent, wherein the water immiscible solvent solubilizes the reactive agent; and a cationic surfactant comprising a quaternary ammonium halide wherein the cationic surfactants emulsify the reactive component in the aqueous phase to form a bi-layer emulsion wherein the composition further comprises cholesterol wherein the ratio of cholesterol to cationic surfactant ranges from about 0.5:1.0 to about 1.5:1.0.

While not being bound to theory, it is believed that the water immiscible solvent comprising the reactive agent serves as a diffusion barrier that minimizes contact between the chemically unstable reactive agent and the aqueous phase. The structured bi-layers surrounding the water immiscible solvent are a further barrier between the reactive agent and the aqueous phase. The bi-layers also serve to keep the reactive agent dispersed within the aqueous continuous phase over the shelf life of the composition to enable the delivery of the reactive agent to the hair in a consumer preferable medium. Further, in the present invention, and presented in all of the examples, for the formation of appropriate bi-layers, to mitigate hydrolysis etc., the present invention surprisingly determined the use of a combination of a quaternary ammonium halide with cholesterol in a specific ratio, in order to achieve the present invention.

Art Rejections

35 U.S.C. § 103(a)

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a) Claims 1-6, 10-21 and 24-30 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Zysman et al, U.S. 5,362,494, collectively "Zysman" in view of US. 5,525,332 to Gough et al., collectively "Gough". The Examiner has asserted that it would have been obvious for one of skill in the art to incorporate the azolactone functionalized polymers or other cosmetic agents functionalized with azolactone in the aqueous dispersion of Zysman containing amphiphilic lipids in combination with other charge lipids such as cholesterol because Gough teaches that the hair conditioning compounds containing azolactone functionalized polymers are useful in achieving a greater degree of chemical bonding of the cosmetic agent with the substrate due to the electrophilic nature and thus achieve an enhanced degree of hair conditioning and styling (col. 7, lines 25-49). Applicants respectfully traverse this rejection.

Zysman discloses nonionic amphiphilic compounds derived from glycerol containing several lipophilic chains (Col 1, lines 7-9) and their broad uses as dispersing agents, emulsifying agents or washing agents (Col 3, lines 38-41). Some of these glycerol compounds are capable of forming vesicles having a lamellar structure (Col 4, lines 33-40) which consist of a lipid phase consisting of one or more lamellae encapsulating a phase E (Col 4 lines 51-54). Moreover, other ionic amphiphilic lipids or nonionic amphiphilic lipids may be combined in the lipid phase with the glycerol compounds (Col 5 lines 23-26).

Zysman teaches the incorporation of an active agents within the lipid phase of the lamellae and/or in the phase encapsulated by the lamellae (col 7, lines 45-48). In the case of oil-in-water emulsions containing the glycerol compounds as emulsifying agents, the fat soluble compounds are entered into the oily phase and the water soluble compounds are entered into the aqueous phase (Col 7 lines 48-55). Zysman also teaches the inclusion of a dispersion of a water-immiscible liquid, which the vesicles physically stabilize which makes it unnecessary to utilize an ordinary emulsifier (Col 12, lines 19-24). Additionally, the water-immiscible liquid can contain one or more lipophilic active compounds (Col 12, lines 58-59). Numerous active compounds are claimed (see Table, columns 7-12) including thioglycolic acid, cysteamine, N-acetylcysteamine and glycerol thioglycolate (col 11, lines 63-69).

Applicants would like to point out that Zysman teaches the 'basics' of the 'art' of bi-layer structures (in the context for use with the glycerol compounds), but this is not the novelty and unobvious invention that is in the present invention. The nucleophilic thiol compounds, as described in Zysman, are generally stable to hydrolysis and therefore are by far the easiest reactive compounds to stabilize within an aqueous medium. Indeed, one of skill in the art is familiar with the fact that they are already utilized within aqueous formulas today (w/o needing protection from a water immiscible solvent within a bi-layer emulsion) including commercially

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available permanent wave products -- the nucleophilic thiols inherent instability lies in their propensity to oxidize in the presence of atmospheric oxygen, but this can be solved via filling under nitrogen, airtight containers etc.

In contrast, in the present invention, as now amended, requires the specific combination of a cationic surfactant comprising a quaternary ammonium halide with cholesterol, and further requires that the ratio of cholesterol to cationic surfactant ranges from about 0.5:1.0 to about 1.5:1.0. Importantly, despite the 'general list' of agents listed in Zysman, none of them comprise the surprising discovery of the present invention in that the specific ratio of cholesterol to a quaternary ammonium halide will provide for the formation of appropriate bi-layers (to mitigate hydrolysis, etc). There is no disclosure in Zysman regarding this specific ratio of cholesterol to quaternary ammonium halide. The mere recitation in Zysman that teaches 0.5 to 50% vesicle forming lipid, therefore optimizing the amount of solvents, active substances, and additional lipids would clearly not lead one of skill in the art to the specific and distinct ratio and combination of the present invention, without undue experimentation which still would not have led to the surprising benefits of the present invention.

Zysman fails to teach a reactive agent comprising the claimed electrophilic group in the composition containing aqueous dispersion of lipid vesicle. However, the Examiner has stated Gough teaches compositions containing vinyl azolactone and methacryloyl polymethylsiloxane polymer for imparting conditioning benefits to hair and for improved retention of the conditioning agent. The polysiloxane polymer is functionalized with azolactone such that the electrophilic reactive component of azolactone reacts with the nucleophilic reactive sites on the surface of the substrate i.e. hair or keratin fibers. Gough also teaches various polymeric materials that can be functionalized with azloacton. Further, Gough suggest that the azoactone functionalized materials may be soluble or dispersible in organic solvents such as silicones, hydrocarbons etc and can be used is solutions or emulsions. Therefore, the Examiner has asserted that it would have been obvious for one of skill in the art to incorporate the azolactone functionalized polymers or other cosmetic agents functionalized with azolactone in the aqueous dispersion of Zysman containing amphiphilic lipids in combination with other charge lipids such as cholesterol because Gough teaches that the hair conditioning compounds containing azolactone funcitonalized polymers are useful in achieving a greater degree of chemical bonding of the cosmetic agent with the substrate due to the electrophilic nature and thus achieve an enhanced degree of hair conditioning and styling. Applicants respectfully traverse this rejection.

Applicants maintain that Gough does not teach the delivery of the electrophilic azalactone reactive group via inclusion within a water immiscible solvent that is then incorporated within a

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bilayer emulsion to achieve stability, as required by the present invention. Instead, Gough teaches the indiscriminate delivery of the azalactones in a number of plausible ways (most of them likely being judged by one of skill in the art to be chemically unstable for a commercial product, according to the present applicants) including water soluble or water/alcohol soluble azalactones delivered via aqueous or aqueous/alcoholic emulsions (Col 7 lines 49-55), organic soluble azalactones delivered via a mousse- or spray- type product, (Col 7 lines 60-65) or predissolving the azalactone in solvents for incorporation within a general cosmetic composition which may be aqueous or non-aqueous based (Col 8, lines 1-9). Applicant would kindly like to point out that that this is a different interpretation of this section than the Examiner, but Applicant believes this is highly accurate based on the wording used in Gough.

Hence, there is no teaching disclosing the delivery of 'water-sensitive' (See specification column 1, lines 31, column 2 lines 5-14) molecules (Claims 7 and 9) via the present invention for consumer preferred aqueous-based formula delivery and such would clearly not have been obvious to one of skill in the art from the Gough disclosure.

Further, and importantly, Gough also does not teach or suggest the present invention's specific combination of a cationic surfactant comprising a quaternary ammonium halide with cholesterol, and further requires that the ratio of cholesterol to cationic surfactant ranges from about 0.5:1.0 to about 1.5:1.0.

Therefore, Zysman in view of Gough does not disclose nor make obvious the present invention, as now claimed.

b) Claims 9, 10, 22 and 23 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Zysman et al, U.S. 5,362,494, in view of Deppert et al, U.S. 5,525,332, collectively "Deppert".

The Examiner asserts that Zysman fails to teach the claimed reactive compounds containing a nucleophilic reactive group, in particular, thiol groups. However, the Examiner continues by asserting that Zysman suggests incorporating hair-conditioning agents in the aqueous dispersions containing amphiphilic vesicles. Therefore, the Examiner asserts that it would have been obvious for one of an ordinary skill in the art to incorporate the sulfur containing quaternary ammonium compound such as disulhydryl, dithiol or diisothiouranium containing quaternary ammonium conditioners of Deppert in the aqueous dispersions containing amphiphilic vesicles of Zysman.

Applicants would again like to point out that Zysman teaches the 'basics' of the 'art' of bi-layer structures (in the context for use with the glycerol compounds), but this is not the novelty and unobvious invention that is in the present invention. The nucleophilic thiol compounds, as described in Zysman, are generally stable to hydrolysis and therefore are by far the easiest

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reactive compounds to stabilize within an aqueous medium. Indeed, one of skill in the art is familiar with the fact that they are already utilized within aqueous formulas today (w/o needing protection from a water immiscible solvent within a bi-layer emulsion) including commercially available permanent wave products -- the nucleophilic thiols inherent instability lies in their propensity to oxidize in the presence of atmospheric oxygen, but this can be solved via filling under nitrogen, airtight containers etc.

More importantly, in contrast, in the present invention, as now amended, requires the specific combination of a cationic surfactant comprising a quaternary ammonium halide with cholesterol, and further requires that the ratio of cholesterol to cationic surfactant ranges from about 0.5:1.0 to about 1.5:1.0. Importantly, despite the 'general list' of agents listed in Zysman, none of them comprise the surprising discovery of the present invention in that the specific ratio of cholesterol to a quaternary ammonium halide will provide for the formation of appropriate bi-layers (to mitigate hydrolysis, etc). There is no disclosure in Zysman regarding this specific ratio of cholesterol to quaternary ammonium halide. The mere recitation in Zysman that teaches 0.5 to 50% vesicle forming lipid, therefore optimizing the amount of solvents, active substances, and additional lipids would clearly not lead one of skill in the art to the specific and distinct ratio and combination of the present invention, without undue experimentation which still would not have led to the surprising benefits of the present invention.

Deppert discloses processes for conditioning human hair by treatment with selected sulfur containing quaternary ammonium compounds, compositions useful for such processes and novel quaternary compounds useful for the processes. Deppert, while disclosing the use of selected sulfur containing quaternary ammonium compounds, is also silent with regard to the use of selected surfactants and water immiscible solvents to form structured bilayers. Further, as now claimed, there would be no motivation to combine the teachings of Deppert with Zysman, and arrive at the present invention, as both references are silent with regard to the present invention surprising discover that such 'water-sensitive' reactive molecules (can be delivered within a consumer preferred 'aqueous' environment by incorporating them within an anhydrous water immiscible solvent which is then included within a structured bi-layer emulsion, wherein it is preferable that the bi-layers have the same ionic charge as the reactive agent. In column 10, lines 44-49, Deppert mentions very briefly a list of common formulation excipients including coloring agents, fragrances, surfactants, buffers etc., and emulsifying agents. However, in Deppert, there is no mention of structured bi-layers as taught & required in the present invention. Deppert neither discloses or makes obvious the need for the described sulfur containing quaternary ammonium salts to be formulated within an 'anhydrous' environment which is undesirable to the consumer.

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Deppert neither discloses nor makes obvious that such sulfur containing quaternary ammonium salts need or would benefit if they were to be delivered within a consumer preferred 'aqueous' environment by incorporating them within an anhydrous water immiscible solvent which is then included within a structured bi-layer emulsion, wherein it is preferable that the bi-layers have the same ionic charge as the reactive agent. This is the surprisingly discover of the present invention. Therefore, one of skill in the art would not be motivated to combine the teaching of Zysman and Deppert in order to arrive at the present invention, in that neither of these reference, either alone or combination, disclose the present invention's surprising discover that such 'water-sensitive' reactive molecules (those in original Claim 7 and 9, now incorporated into Claim 1) can be delivered within a consumer preferred 'aqueous' environment by incorporating them within an anhydrous water immiscible solvent which is then included within a structured bi-layer emulsion, wherein it is preferable that the bi-layers have the same ionic charge as the reactive agent. Zysman is not directed toward the present invention, as detailed above, and Deppert is even further removed from teaching or suggesting a need to combine the described compounds in Deppert with the teachings of Zysman. Therefore one of skill in the art would not be motivated to combine Zysman with Deppert and arrive at the present invention.

Further, and importantly, both references are silent with regard to the surprising benefit of the present invention in that neither Zysman or Deppert disclose or suggest the present invention's specific combination of a cationic surfactant comprising a quaternary ammonium halide with cholesterol; at a specified ratio of cholesterol to cationic surfactant ranging from about 0.5:1.0 to about 1.5:1.0.

Further, one of ordinary skill in the art would not have been lead or motivated to modify the compositions of Zysman by adding or blending the teachings of Deppert and successfully arrive at the present invention.

No Prima Facie Case

In order to establish a *prima facie* case of obviousness, the Examiner must show that (1) there is some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings, (2) there is a reasonable expectation of success, and (3) all of the limitations of the claims are taught or suggested in the prior art (M.P.E.P. § 2143). In the present case, the Examiner has not provided the requisite motivation to modify either Zysman or Gough or Deppert so as to obtain Applicants' invention. Unlike Applicants, Zysman, Gough or Deppert, or the combination of Zysman with Gough or Zysman with Deppert, do not recognize the surprising benefit of the use of a quaternary ammonium halide in combination with cholesterol at a very

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specific ratio of about 0.5:1.0 to about 1.5:1.0. Applicants disclose an "improved formation of appropriate bi-layers to mitigate hydrolysis etc." wherein Applicants recognize the beneficial interactions of the components of such a system.

Further, Zysman in view of Gough or Zysman in view of Deppert do not teach or suggest all of Applicants' claim limitations and therefore, does not establish a *prima facie* case of obviousness (see MPEP 2143.03). Specifically, Zysman in view of Gough or Zysman in view of Deppert do not teach the claim limitation wherein a cationic surfactant comprises a quaternary ammonium halide and wherein the composition further comprises cholesterol wherein the ratio of cholesterol to cationic surfactant ranges from about 0.5:1.0 to about 1.5:1.0. Clearly Zysman in view of Gough or Zysman in view of Deppert neither disclose nor makes obvious this component of the present invention.

Lastly, even if a *prima facie* case was established, the obviousness argument is overcome by Applicants' showing of unexpected results. Therefore, Applicants' contend that the claimed invention is unobvious and that the rejection should be withdrawn. Further, as Zysman in view of Gough or Zysman in view of Deppert do not recognize the relationship between the quaternary ammonium halide and the cholesterol, as well as the specific ratio required to provide improved benefits, there is no motivation to specifically select quaternary ammonium halide in combination with cholesterol at a specified ratio. Therefore, Zysman in view of Gough or Zysman in view of Deppert neither disclose nor make obvious the present invention.

In summary, neither Zysman in view of Gough nor Zysman in view of Deppert, establish a *prima facie* case of obviousness because there is no suggestion or motivation to modify the references. Secondly, the cited references do not teach or suggest all of Applicants' claim limitations and therefore, does not establish a *prima facie* case of obviousness. Thirdly, even if a *prima facie* case was established, the obviousness argument is overcome by Applicants' showing of unexpected results, i.e. providing surprising benefits by the use of the specified quaternary ammonium halide in combination with cholesterol at a specified and necessary ratio. Therefore, Applicants' contend that the claimed invention is unobvious and that the rejection should be withdrawn.

Therefore, there is no *prima facie* case of obviousness since none of the references, either alone or when combined, teach or suggest all of the Applicant's claim limitations.

In light of the arguments presented herein, it is respectfully submitted that the rejection of the claims under 35 U.S.C. § 103(a) be withdrawn.

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Conclusions

Applicants have made an earnest effort to place their application in proper form and distinguish their claimed invention from the references which were applied in the May 8, 2003 Office Action. WHEREFORE, consideration of this application, withdrawal of the rejections under 35 U.S.C § 112 and 103, and allowance of the pending Claims are respectfully requested.

Respectfully submitted,

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